Baxter

April 6, 2021

Via Electronic Mail and First-Class Mail

Bryant Smalley
CR-ERNS Coordinator
U.S. Environmental Protection Agency, Region 6
1201 Elm Street, Suite 500
Mail Code: SEDER
Dallas, TX 75270
Smalley.bryant@Epa.gov

RE: 40 C.F.R. § 302.8(f) – Follow-Up Notification, Baxter Healthcare Corporation, Mountain Home, Arkansas

Dear Mr. Smalley:

On February 11, 2020, Baxter Healthcare Corporation ("Baxter") identified a continuous release of ethylene oxide ("EO") at its manufacturing facility in Mountain Home, Arkansas and made an initial telephone notification of the continuous release, pursuant to the U.S. Environmental Protection Agency's ("EPA") regulations at 40 C.F.R. § 302.8(d) and 40 C.F.R. § 355.32(a). On March 12, 2020, Baxter provided its initial written notification pursuant to 40 C.F.R. § 302.8(e) to EPA Region 6, the State Emergency Response Commission ("SERC"), and the Local Emergency Planning Committee ("LEPC").

Within 30 days of the first anniversary date of the initial written notification, 40 C.F.R. § 302.8(f) requires the facility to evaluate the reported release "to verify and update the information submitted in the initial written notification." Accordingly, Baxter now submits follow-up notification to EPA, Region 6.

I. FACILITY INFORMATION, 40 C.F.R. § 302.8(f)(1)

The facility information provided for the Baxter Mountain Home facility ("the Facility") in the initial written notification remains accurate, with one exception. The site manager has changed, and the site manager is now: Richard Titus, who can be reached at (870) 424-5210. The remainder facility information provided remains accurate and is repeated here for ease of reference.

The Facility is located at 1900 North Highway 201, Mountain Home, AR 72653 (36°21'36.4"N, 92°23'16.9"W). Baxter Healthcare Corporation's Dun and Bradstreet number is 024543730. The Dun and Bradstreet number for Baxter's parent company, Baxter International Inc., is 005146311. The Incident Report Number assigned by the NRC to the release incident is 1271013.

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II. SURROUNDING COMMUNITY, 40 C.F.R. § 302.8(f)(2-3)

The information provided in the initial written notification on the surrounding community remains accurate and is repeated here for ease of reference.

The population density within a one-mile radius of the Facility is estimated to be more than 1,000 persons. Baxter has identified the following sensitive populations located within a one-mile radius of the Facility:

- Nelson-Wilks-Herron Elementary School (618 N. College Street in Mountain Home, AR) (approximately 0.8 miles from the Facility);
- Mountain Home VA Clinic (759 Highway 62 East, Suite 331, Mountain Home, AR) (approximately 0.9 miles from the Facility); and
- Noah's Ark Preschool (202 Springwood Dr, Mountain Home, AR) (approximately 0.6 miles from the Facility).

Baxter has not identified sensitive ecosystems within a one-mile radius of the Facility.

III. RELEASE DETAILS, , 40 C.F.R. § 302.8(f)(4)

The information provided in the initial written notification on the release remains accurate with a few minor changes. Below is what Baxter reported in its initial written notification with edits indicated with the strike-outs and underlined text.

EO is on the list of Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA") hazardous substances, as well as the list of extremely hazardous substances under the Emergency Planning and Community Right-to-Know Act ("EPCRA"). The Chemical Abstracts Service Registry Number for EO is 75-21-8.

The Facility manufactures medical devices and uses EO sterilization as a part of the manufacturing process. The Facility has a Minor Source Air Permit issued by the Arkansas Department of Environmental Quality ("ADEQ") (Permit No. 0544-AR-16), which sets permit limits for EO. The Facility had a release of EO above those permit limits from the stacks of a north catalytic oxidizer and south catalytic oxidizer, which treat exhaust air from aeration rooms that are used in the sterilization process. Each stack has a height of 43 feet above ground level. The environmental medium affected by the release is outdoor air.

On February 11, 2020, Baxter conducted emissions testing of the Facility's two catalytic oxidizers and identified air emissions of EO in excess of the pounds per hour emission limits in the Facility's air permit. The permit limits EO emissions of the Facility's catalytic oxidizers to 0.184 pounds per hour per catalytic oxidizer. The testing conducted on February 11 indicated that the emissions rate may be as high as 2.1 pounds per hour at one catalytic oxidizer and as high as 1.3 pounds per hour at the second catalytic oxidizer. As per standard testing protocol, this testing was done at near maximum operating capacity and not normal operating conditions.

On February 13, 2020, the Facility's catalytic oxidizer vendor, the CMM Group, LLC ("CMM") conducted an inspection of the Facility's two catalytic oxidizers to identify the root cause of the emission exceedances. ~~While the root cause analysis is still ongoing,~~ CMM ~~indicated~~ concluded that the most likely cause of the decreased performance of the catalytic oxidizers – and the associated increase of EO emissions – was a loss of approximately 1 inch of catalyst across all of the catalyst beds in both units due to settling and attrition. This caused a continuous, without interruption, and stable in quantity and rate release that was incidental to normal operation during the time the catalyst beds experienced the settling and attrition. The catalytic oxidizers operate continuously, and EO emissions would, therefore, have occurred continuously under normal operating conditions.

At the time of the February 11, 2020 testing, and at near maximum capacity, the two catalytic oxidizers had a total release of 3.4 pounds per hour, which would equate to approximately 81.6 pounds if extrapolated for a 24-hour period. This is approximately 73 pounds per day higher than the permit limits for the catalytic oxidizers. Upon discovery of this release, the Facility commenced corrective action and began an orderly wind down of its sterilization operations. The sterilization process is a two-step process:

1. Medical devices are put in sterilization vessels where EO is added to sterilize the devices. A wet scrubber is used to control EO emissions from the chambers.
2. After the sterilization process is complete, the sterilized product then goes to aeration chambers where off gassing occurs. That off gassing vents to the two catalytic oxidizers, where the release above permit limits occurred.

Upon receiving the test results on February 11, sterilized product was already in the sterilization vessels and the aeration chambers. The Facility began winding down its operations by ceasing any new sterilization activity in the vessels – no new EO was applied to product. Because the off gassing process cannot be stopped, it continued to run its course. The continuous and stable release occurred through February 22, 2020 until the off gassing process completed. At that point, the catalytic oxidizers were brought down, and the continuous releases above permit limits ceased.

Pursuant to a temporary variance granted by ADEQ, the Facility restarted the catalytic oxidizers as the primary emission control technology for the aeration chambers and then added two thermal oxidizers in addition to those catalytic oxidizers on the same waste streams to further reduce EO emissions and achieve EO emissions below the permit limits. Pursuant to the temporary variance, the Facility also added a series of absorbent dry beds to further reduce EO emissions from the Facility's wet scrubber. Although the Facility has not performed testing on the scrubber that revealed any permit exceedances, the Facility chose to adopt additional EO emission reduction measures for the scrubber in order to further reduce EO emissions at the Facility. Because of the additional control technology, the Facility is operating within its permit limits and no longer has continuous releases. Baxter continues to operate additional emission control equipment, including dry beds and a thermal oxidizer, pursuant to a grant of interim authority by ADEQ.

The upper and lower bounds of the normal range of EO emissions from the catalytic oxidizers, without considering the ~~recent~~ February 2020 exceedance, ~~is~~ was approximately 1,376 pounds to 3,223 pounds per year. (1,376 pounds is the estimated emissions based on the 2016 performance testing, of the catalytic oxidizers, and 3,223 pounds is the allowable EO emissions limit for the catalytic oxidizers pursuant to the air permit.) From February 11, 2020 to February 22, 2020, the Facility had additional emissions up to 876 pounds, which assumes that the additional increase of 73 pounds per day continued during the entire 12-day period. The failure in the catalytic oxidizers caused a reduced destruction removal efficiency ("DRE"). Based on available data and engineering judgment the reduced DRE remained constant and continuous during this 12-day period. Because EO emissions from the product in the aeration rooms decreased over time and no freshly sterilized product was placed in the aeration rooms, the amount of EO released decreased during the 12-day period. Therefore, 73 pounds per day is the upper bound of emissions that occurred during that time period. These estimates are based on knowledge of the Facility's operations, release data, and best professional judgment.

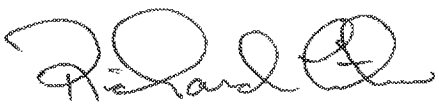
It is unknown when the catalyst bed decreased due to settling and/or attrition and the decreased performance of the catalytic oxidizers began. The last required performance testing on the catalytic oxidizers occurred in July 2016, which confirmed compliance with the permit limits. Pursuant to the permit, the Facility was required to replace the catalyst bed every five years beginning after that initial compliance test. Replacement of the catalyst bed was thus not due until July 2021. It is, therefore, not anticipated or estimated that the detected rate of 73 pounds per day above the permit limits occurred during the entire preceding year, but 73 pounds per day would be the upper bound. Should Baxter's ongoing investigation of the incident reveal additional information that would allow Baxter to better estimate the total annual release, Baxter will supplement this report as appropriate. Baxter did not discover any additional information that would allow it to better estimate the total annual release.

This continuous release is no longer occurring due to the corrective actions taken by Baxter at the Facility. Because the continuous release ended on February 22, 2020 and is no longer occurring, updated information is not provided on (1) the upper and lower bounds of the normal range of the release over the previous year, or (2) the estimated total annual amount that was released in the previous year. Baxter is working closely with ADEQ on all related issues and will be performing additional testing on its emission control equipment this year.

If you have any questions regarding this letter, please contact Richard Titus at (870) 424-5210.

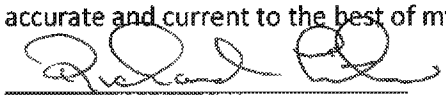
Baxter

Respectfully submitted,



Richard Titus
Site Director, Mountain Home Facility
Baxter Healthcare Corporation
1900 North Highway 201
Mountain Home, AR 72653
Telephone: 870-424-5210
Email: richard_titus@baxter.com

I certify that the hazardous substance releases described herein occurred continuously and were stable in quantity and rate under the definitions in 40 C.F.R. § 302.8(b) and that all submitted information is accurate and current to the best of my knowledge.



Richard Titus

Baxter

March 12, 2020

Via Electronic Mail and First-Class Mail

Bryant Smalley
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U.S. Environmental Protection Agency, Region 6
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ADEM Phone: 501-683-6700
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Chris.foreman@adem.arkansas.gov

Phillip Johnson
LEPC for Baxter County
170 Dillard Drive
Midway, AR 72651
(870) 481-6252
oemdirector@baxtercounty.org

RE: Continuous Release Notification, Baxter Healthcare Corporation, Mountain Home, Arkansas

To Whom It May Concern:

On February 11, 2020, Baxter Healthcare Corporation ("Baxter") identified a continuous release of ethylene oxide ("EO") at its manufacturing facility in Mountain Home, Arkansas. The release of EO was in excess of the 10 pounds / 24 hour reportable quantity threshold for EO under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA") and the Emergency Planning and Community Right-to-Know Act ("EPCRA"). Accordingly, on February 11, 2020, Baxter made an initial telephone notification of the continuous release, pursuant to the U.S. Environmental Protection Agency's ("EPA") regulations at 40 C.F.R. § 302.8(d) and 40 C.F.R. § 355.32(a).

Within 30 days of the initial telephone notification, 40 C.F.R. § 302.8(e) requires the facility to make an initial written notification to the EPA regional office for the geographic area in which the facility is located. In addition, 40 C.F.R. § 355.32(a) requires that this initial written notification also be

submitted to the State Emergency Response Commission ("SERC"), and Local Emergency Planning Committee ("LEPC"). Accordingly, Baxter now submits this initial written notification to EPA, Region 6, the Arkansas SERC, and the LEPC.

I. FACILITY INFORMATION

The Baxter Mountain Home facility ("the Facility") is located at 1900 North Highway 201, Mountain Home, AR 72653 (36°21'36.4"N, 92°23'16.9"W). Baxter Healthcare Corporation's Dun and Bradstreet number is 024543730. The Dun and Bradstreet number for Baxter's parent company, Baxter International Inc., is 005146311. The site manager, Mark Meyer, can be reached at (870) 424-5210.

II. CASE NUMBER

The Incident Report Number assigned by the NRC to the release incident is 1271013.

III. SURROUNDING COMMUNITY

The population density within a one-mile radius of the Facility is estimated to be more than 1,000 persons.

Baxter has identified the following sensitive populations located within a one-mile radius of the Facility:

- Nelson-Wilks-Herron Elementary School (618 N. College Street in Mountain Home, AR) (approximately 0.8 miles from the Facility);
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- Noah's Ark Preschool (202 Springwood Dr., Mountain Home, AR) (approximately 0.6 miles from the Facility).

Baxter has not identified sensitive ecosystems within a one-mile radius of the Facility.

IV. RELEASE DETAILS

EO is on the list of CERCLA hazardous substances, as well as the list of extremely hazardous substances under EPCRA. The Chemical Abstracts Service Registry Number for EO is 75-21-8.

The Facility manufactures medical devices and uses EO sterilization as a part of the manufacturing process. The Facility has a Minor Source Air Permit issued by the Arkansas Department of Environmental Quality ("ADEQ") (Permit No. 0544-AR-16), which sets permit limits for EO. The Facility had a release of EO above those permit limits from the stacks of a north catalytic oxidizer and south catalytic oxidizer, which treat exhaust air from aeration rooms that are used in the sterilization process. Each stack has a height of 43 feet above ground level. The environmental medium affected by the release is outdoor air.

On February 11, 2020, Baxter conducted emissions testing of the Facility's two catalytic oxidizers and identified air emissions of EO in excess of the pounds per hour emission limits in the Facility's air

permit. The permit limits EO emissions of the Facility's catalytic oxidizers to 0.184 pounds per hour per catalytic oxidizer. The testing conducted on February 11 indicated that the emissions rate may be as high as 2.1 pounds per hour at one catalytic oxidizer and as high as 1.3 pounds per hour at the second catalytic oxidizer. As per standard testing protocol, this testing was done at near maximum operating capacity and not normal operating conditions.

On February 13, 2020, the Facility's catalytic oxidizer vendor, the CMM Group, LLC ("CMM") conducted an inspection of the Facility's two catalytic oxidizers to identify the root cause of the emission exceedances. While the root cause analysis is still ongoing, CMM indicated that the most likely cause of the decreased performance of the catalytic oxidizers – and the associated increase of EO emissions – was a loss of approximately 1 inch of catalyst across all of the catalyst beds in both units due to settling and attrition. This caused a continuous, without interruption, and stable in quantity and rate release that was incidental to normal operation during the time the catalyst beds experienced the settling and attrition. The catalytic oxidizers operate continuously, and EO emissions would, therefore, have occurred continuously under normal operating conditions.

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1. Medical devices are put in sterilization vessels where EO is added to sterilize the devices. A wet scrubber is used to control EO emissions from the chambers.
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order to further reduce EO emissions at the Facility. Because of the additional control technology, the Facility is operating within its permit limits and no longer has continuous releases.

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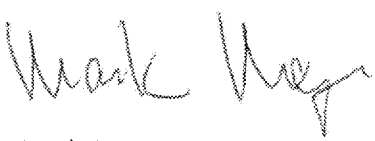
This continuous release is no longer occurring due to the corrective actions taken by Baxter at the Facility. If any additional permit exceedances occur above the reportable quantities, Baxter will submit the additional required notifications.

V. CLOSING

If you have any questions regarding this letter, please contact Mark Meyer at (870) 424-5210.

Respectfully submitted,



Mark Meyer
Site Director, Mountain Home Facility
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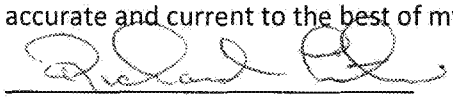
If you have any questions regarding this letter, please contact Richard Titus at (870) 424-5210.

Respectfully submitted,

Richard Titus
Site Director, Mountain Home Facility
Baxter Healthcare Corporation
1900 North Highway 201
Mountain Home, AR 72653
Telephone: 870-424-5210
Email: richard_titus@baxter.com

I certify that the hazardous substance releases described herein occurred continuously and were stable in quantity and rate under the definitions in 40 C.F.R. § 302.8(b) and that all submitted information is accurate and current to the best of my knowledge.



Richard Titus